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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,985	11/03/2000	Dirk M. Anderson	2874-B	6890

22932 7590 07/28/2006

IMMUNEX CORPORATION
LAW DEPARTMENT
1201 AMGEN COURT WEST
SEATTLE, WA 98119

EXAMINER

STANDLEY, STEVEN H

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,985	ANDERSON ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 09 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9, 11, 13, 15-18, 20, 21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 17 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 9, 11, 13, 15, 16, 18, 20, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/04&5/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed 5/09/06 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Objections/Rejections: Withdrawn

Claim Rejections - 35 USC § 112

Rejection of claims 5, 9, 11, 13, 15, 16, 18, 20, 25, and 26 under 35 USC § 112, 2nd paragraph for omitting essential steps is withdrawn due to applicant's amendment.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

Rejection of claim 5, 9, 11, 13, and 15 under 35 USC § 112, 1st paragraph, written description is maintained for the reasons made of record in the office action dated 11/17/05. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the specification and claims satisfy the written description. Applicant is referred to pages 2-3 of the prior office action in which the stringency was described as encompassing variants with 63-65 percent identity based on a 1% mismatch conferring a 1 degree drop in T_m (see appendix A from the last action). SEQ ID NO: 1 of the instant application is about 3100 base pairs and has a

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time calculated at 99 degrees. More than a thousand base pairs of SEQ ID NO: 1 are non-coding. Therefore, if all the variation, or mismatch, in the DNA sequence of SEQ ID NO: 1 resides in the coding region, the resulting polypeptides encompassed by the conditions recited would be far more than merely 63-65 percent variation estimated for the DNA variants encompassed as well. As argued in the previous office action, applicant does not have written description for variants encompassing such low DNA (and polypeptide) sequence identity. Furthermore, a recitation of 90% in the claim does not have adequate written description in the specification. Applicant has not defined any structural features of the instant polypeptide as they relate to its function of binding RANKL. The skilled artisan cannot envision the detailed changes encompassed by the genus claimed that function as recited by the claims.

Rejection of claims 5, 9, 11, 13, 15, 16, 18, 20, 25, and 26 under 35 USC § 112, 2nd paragraph, is maintained for the reasons made of record in the office action dated 11/17/05. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that amendments provide for explicit hybridization and wash conditions. However, as argued by the examiner, the conditions do not indicate the presence of absence of formamide, magnesium or its concentration, the ph of the wash. Therefore claims 5 and 13 remain indefinite. The other claims are indefinite as they depend from indefinite claims.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Janet Andre can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven Standley, Ph.D.

7/21/05


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER